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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,434	02/11/2004	Rafail Zubok	532/2x6 (F-280 Cont V)	2903
27538	7590	06/24/2004	EXAMINER	
KAPLAN & GILMAN, L.L.P.			MILLER, CHERYL L	
900 ROUTE 9 NORTH			ART UNIT	PAPER NUMBER
WOODBIDGE, NJ 07095			3738	

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/776,434

Applicant(s)

ZUBOK ET AL.

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/11/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5, and 10-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4, 10, and 11 recite the limitation "the aggregate" in lines 2, 11, and 2 respectively. There is insufficient antecedent basis for this limitation in the claims. Claims 5 and 12-17 depend upon claims 4, 10 and 11, and therefore inherit all problems with the claims.

It is also noted to the applicant that claim 12 is missing a period at the end of the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 7-13, and 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by William et al. (US 2004/0010316 A1). Referring to claims 1 and 10, William discloses an apparatus (10) for replacing a portion of an intervertebral disc comprising a first member (12)

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having a first vertebral contact surface (16) and a first articulation surface (surface 60 of 18), a second member (14) having a second vertebral contact surface (20) and a second articulation surface (surface 120 of 22), wherein an intervertebral disc space is defined between first and second endplates of the first and second vertebral bones, and at least one of the articulation surfaces is saddle shaped (see fig.6, 8, 12, 18; saddle being interpreted by its broadest definition as a ridge connecting two higher elevations), and wherein the articulation surfaces (60, 120) are sized and shaped to engage one another (fig.2, 20) and enable the vertebral bones to articulate in flexion, extension, and lateral bending (fig.21, 23, 24).

Referring to claims 2-5, 7-9, 11-13, and 15-17, William discloses the articulation surfaces (60, 120) to both be contiguously saddle shaped (saddle being interpreted by its broadest definition as a ridge connecting two higher elevations), both to be bearing surfaces (see figures), which permit the vertebral bones to articulate in flexion, extension, lateral bending, and rotation through a range of angles without displacing the bones away from each other until outside the range of angles ([0067, 0071, 0078], freely moves along arcs A1 and A2 and A3 and A4, all together, therefore rotation is inherently occurring, and since flanges may be positioned to limit movement, including rotation, some rotation is occurring through a limited range as claimed).

Claims 1-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Ferree et al. (US 2004/0024462 A1). Referring to claims 1 and 10, Ferree discloses an apparatus for replacing a portion of an intervertebral disc [0002] comprising a first member (top member in figures) having a first vertebral contact surface (top surface) and a first articulation surface (bottom surface), a second member (bottom member in figures) having a second vertebral contact surface

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(bottom surface) and a second articulation surface (top surface), wherein an intervertebral disc space is defined between first and second endplates of the first and second vertebral bones, and at least one of the articulation surfaces is saddle shaped (see figures; [0007]), and wherein the articulation surfaces are sized and shaped to engage one another and enable the vertebral bones to articulate in flexion, extension, and lateral bending [0007, 0024].

Referring to claims 2-5, 7-9, 11-13, and 15-17, Ferree discloses the articulation surfaces to both be contiguously saddle shaped (see figures; 0007]), both to be bearing surfaces, which permit the vertebral bones to articulate in flexion, extension, lateral bending, and rotation through a range of angles without displacing the bones away from each other until outside the range of angles ([0007, 0024], since rotation is disclosed to be limited, it inherently occurs to some level through a range as claimed).

Referring to claims 6 and 14, Ferree discloses at least one of the saddle shaped articulation surfaces (top member in figures) to be defined by a concave arc (top member's bottom surface seen in fig.3b, 4a) having a radius of curvature A about a first axis substantially perpendicular to an anterior-posterior plane of the spinal column, and a convex arc (top member's bottom surface seen in fig.3a, 4d, 4e) having a radius of curvature B about a first axis substantially perpendicular to a lateral plane of the spinal column, and/or defined by (bottom member in figures) a convex arc (bottom member's top surface seen in fig.3b, 4a) having a radius of curvature C about a second axis substantially perpendicular to the anterior-posterior plane of the spinal column, and a concave arc (bottom member's top surface seen in fig.3a, 4d, 4e) having a radius of curvature D about a second axis substantially perpendicular to the lateral plane of the spinal column.

Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Shelokov (USPN 6,039,763). Referring to claims 1 and 10, Shelokov discloses an apparatus for replacing a portion of an intervertebral disc (col.1, lines 4-6) comprising a first member (1) having a first vertebral contact surface (2) and a first articulation surface (3), a second member (10) having a second vertebral contact surface (11) and a second articulation surface (12), wherein an intervertebral disc space is defined between first and second endplates of the first and second vertebral bones (fig.7), and at least one of the articulation surfaces (3, 12) is saddle shaped (fig.1c, 2c, 7), and wherein the articulation surfaces are sized and shaped to engage one another (fig.3a-4b, 7) and enable the vertebral bones to articulate in flexion, extension, and lateral bending (col.4, lines 13-16).

Referring to claims 2-5, 7-9, 11-13, and 15-17, Shelokov discloses the articulation surfaces (3, 12) to both be contiguously saddle shaped (see figures), both to be bearing surfaces, which permit the vertebral bones to articulate in flexion, extension, lateral bending, and rotation through a range of angles without displacing the bones away from each other until outside the range of angles (col.4, lines 13-16; col.5, lines 47-53).

Referring to claims 6 and 14, Shelokov discloses (see figs.1a-1c, 2a-2c, and 7) at least one of the saddle shaped articulation surfaces (3) to be defined by a concave arc (arc extending from 4 to 5 in fig.1b) having a radius of curvature A about a first axis substantially perpendicular to an anterior-posterior plane of the spinal column, and a convex arc (arc 3 seen in fig.1a) having a radius of curvature B about a first axis substantially perpendicular to a lateral plane of the spinal column, and/or defined by (on member 10) a convex arc (arc 12 in fig.2b) having a radius

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of curvature C about a second axis substantially perpendicular to the anterior-posterior plane of the spinal column, and a concave arc (arc 12 in fig.2a) having a radius of curvature D about a second axis substantially perpendicular to the lateral plane of the spinal column.

Conclusion

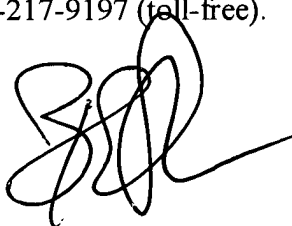
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Cheryl Miller


BRUCE SNOW
PRIMARY EXAMINER